REMARKS

I. Election

In response to the election of species requirement, applicants elect, with traverse, the following:

A. In claims 19, 21, 22, 23 and 24: "short bacteriophage tail fiber"

B. In claim 20: "T4"

C. In claim 25: "SEQ ID NO: 5"

D. In claim 26: "T4"

All claims are generic and read on the elected species.

II. Traversal

Applicants traverse the election of species as set forth above. The grounds for traversal are three-fold. First, the IPRP indicates that there was no lack of unity among the claims, which though amended here, are substantially similar to those examined during the international phage. The examiner has offered no explanation why the IPRP does not control.

Second, the examiner argues that PCT Rule 13.2 permits examination of a single product, method of using said product, and a method of making said product. The examiner argues that the claims are directed to multiple products (and methods). This is incorrect. PCT Rule 13.2 states: "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features" shall mean those technical features that define a contribution which each of the claimed inventions,

considered as a whole, makes over the prior art." There is no mention in this rule of "single" or "multiple" products or methods. Rather, there is only reference to "special technical features" and "unity."

Third, there is no argument that the art cited in the International Search Report undermines the common inventive step of detecting endotoxin via an indirect detection mechanism. WO 2004/001418 was filed in German and published on December 31, 2003 and thus after the priority date of the present invention. Neither Thomassen nor Baxa nor U.S. Patent 6,436,653 relate to the detection of endotoxin.

WO 03/000888 discloses a method for a selective purification of endotoxin. In contrast, the present invention provides a method for the detection of endotoxin. Thus, the object of both methods is completely different and a person skilled in the art would have no motivation to develop a detection method out of a purification method.

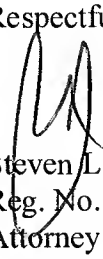
Moreover, the methods of the present invention differs significantly from the method as disclosed in WO 03/000888. The selective purification of endotoxin as disclosed in WO 03/000888 is a ***direct*** method, where a sample containing endotoxin is incubated with a bacteriophage tail protein. The bound endotoxin-bacteriophage tail protein-complex is then separated. In contrast, the methods of the present invention the endotoxin rely on a sample immobilised on a surface in step a), which is then incubated with the bacteriophage tail protein (step b). Finally (step c), the surface-bound endotoxin-bacteriophage tail protein is detected indirectly, such as with spectroscopic methods, ELISA, chemical or enzymatic detection reaction of endotoxins or cleaved-of endotoxin components, or by means of capacitance measurements.

If attempting to develop a method of detecting endotoxin, the skilled artisan would be motivated to detect endotoxins with ***directly*** to receive an immediate and undampened signal

from the endotoxin. Indirect methods, such as in the present invention, would not appear desirable since the skilled artisan would expect the signal to be reduced due to the indirect nature of the detection. Accordingly, there would be significant technical prejudice against use of an indirect detection method. However, the methods of the present invention have been shown to provide a very specific analysis of endotoxins. These methods advantageously permit the surface with the bound endotoxin and the bacteriophage tail protein to be washed, and thus non-specific proteins can be removed. Furthermore, indirect detection in form of an ELISA using a specific first and second antibody allows a signal improvement. Consequently, and as already stated in the IPRP, methods for the detection of endotoxin (*e.g.*, claim 16) are inventive over WO 03/000888 and the other art cited in the ISR. As a consequence, the method is also inventive across all species of groups A to D as outlined in the office action. Hence, the unity objection is further unjustified.

Therefore, reconsideration of the lack of unity is requested. The examiner is invited to contact the undersigned regarding any questions on this submission.

Respectfully submitted,



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